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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,767	04/07/2005	Rajinder Singh	02-438-B1	9966

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EXAMINER	
FREISTEIN, ANDREW B	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/530,767

Applicant(s)

SINGH ET AL.

Examiner

Andrew B. Freistein

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25,28-34 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 30-34 is/are rejected.
- 7) ☒ Claim(s) 25 and 28-34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

The amendment filed 2/6/2007 was entered. Claims 25, 28-34 and 38-41 are pending. Claims 1-24, 26, 27 and 35-37 were cancelled.

#### ***Restriction Requirement***

Applicant traverses the restriction requirement, because the 35 USC 102(b) rejection was traversed. Examiner maintains the anticipation rejection and provides several more compositions that anticipate claim 25. As a result the restriction requirement is maintained as follows:

#### ***Status of the Claims***

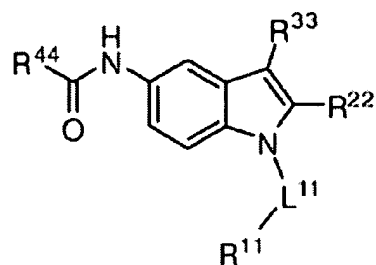
Claims 25 and 28-34 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

#### **Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

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Compositions comprising compounds of the Formula (I),



, wherein:

 $L^{11}$  is a bond; $R^{11}$  is H; $R^{22}$  and  $R^{33}$  are as defined in claim 25; and

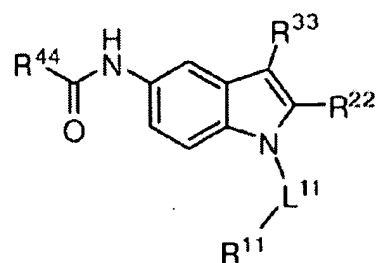
$R^{44}$  is an optionally substituted  $C_{3-6}$  monocyclic heteroaryl containing at least one N, O or S atom; or an optionally substituted  $C_{3-6}$  monocyclic heterocycle containing at least one N, O or S atom;

$R^{50}$ ,  $R^6$ ,  $R^7$  and  $R^{23}$  are each independently as defined in claim 25.

#### Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:

Compositions comprising compounds of the Formula (I),



, wherein:

 $L^{11}$  is carbonyl; $R^{11}$  is phenyl or  $C_{4-6}$ -heteroaryl;

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**R<sub>44</sub>** is independently H or optionally substituted C<sub>1-6</sub> alkyl, C<sub>3-7</sub>cycloalkyl, C<sub>3-7</sub> monocyclic aryl, C<sub>3-7</sub> heterocycloalkyl, C<sub>3-7</sub> cycloalkanone, C<sub>7-13</sub> bicyclic aryl, C<sub>5-13</sub> bicyclic heteroaryl, C<sub>5-13</sub> bicyclic heterocycle.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 25-35 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiophene, furan, phenyl, pyridine, cyclopropane, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

***Pending Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Pending Rejection) Claims 25-27, 30 and 35 are rejected under 35

U.S.C. 102(b) as being anticipated by Johnson et al., WO 98/06402. Claims 26, 27 and

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35 were cancelled. The rejection of claim 30 is withdrawn. Claims 26-27 and 35 were cancelled. The rejection of claim 25 is maintained and made FINAL.

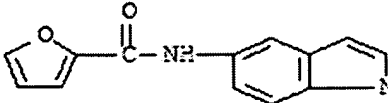
Applicant traverses the rejection, because the cited compound is an intermediate and is not present with a "pharmaceutically acceptable carrier, excipient or diluent."

According to the specification, "pharmaceutically acceptable" is defined to be:

*Solutions or suspensions used for parenteral, intradermal, subcutaneous, or topical application can include the following components: a sterile diluent such as water for injection, saline solution, fixed oils, polyethylene glycols, glycerin, propylene glycol or other synthetic solvents...*

Further, one of ordinary skill in the art would not consider dichloromethane, ethyl acetate, methanol or tetrahydrofuran (THF) as a diluent for the preparation of a pharmaceutically acceptable composition.

Examiner respectfully disagrees with Applicant. Originally, the claims read, "A pharmaceutical composition comprising..." However, the term "pharmaceutical" was deleted and the claim was amended to claim a composition comprising a pharmaceutically acceptable carrier, excipient, or diluent together with a compound of formula (I). The claim is not drawn to a pharmaceutical composition, but any composition.

The compound  is disclosed in the reference in ethyl

acetate, which is a composition. Further, the mixture was diluted with water and sodium chloride. Pharmaceutically acceptable carriers, excipients and diluents as well as

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formulations are also disclosed (see WO 98/11895, p. 69, Ex. 111; and p. 198, line 28 - p. 208).

Additionally, according to the specification, a pharmaceutically acceptable carrier, excipient or diluent is water. In the preparation of the prior art compound, water is used and is part of the composition.

Applicant argues that the FDA guidelines on the safety of pharmaceutical compositions teach that ethyl acetate and THF are not pharmaceutically acceptable. Whether ethyl acetate or THF are pharmaceutically acceptable is irrelevant, because the composition can "comprise" anything in addition to the compound and a pharmaceutically acceptable carrier, excipient or diluent. Here, the composition comprises water, sodium chloride and the compound. Therefore, the rejection is maintained and made FINAL.

### ***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

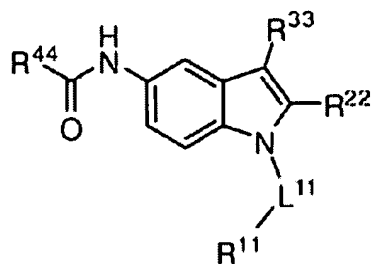
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

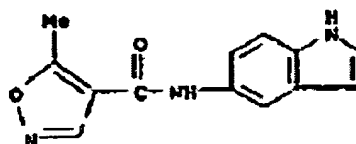
(1) Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Bartlett et al., US Pat. No. 5,494,911.

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The instant invention is drawn to a composition comprising a pharmaceutically acceptable carrier, excipient or diluent together with a compound of the formula,



, wherein  $L^{11}$  is a covalent bond;  $R^{11}$  is H;  $R^{22}$  is H;  $R^{33}$  is H; and  $R^{44}$  is an optionally substituted  $C_{3-6}$  monocyclic heteroaryl containing a N, O or S atom, wherein the optional substituents are  $R^6$  groups;  $R^6$  is  $R^{50}$ ; and  $R^{50}$  is  $CH_3$ .

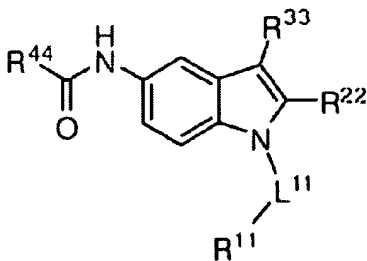


Bartlett et al. disclose the compound: and

pharmaceutically acceptable carrier (see col. 7, line 54 – col. 8, line 18; and col. 23, Ex. 41).

(2) Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Frederickson et al., US 2005/0124620 A1.

The instant invention is drawn to a composition comprising a pharmaceutically acceptable carrier, excipient or diluent together with a compound of the formula,

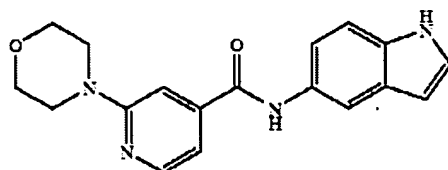


, wherein  $L^{11}$  is a covalent bond;  $R^{11}$  is H;  $R^{22}$  is H;  $R^{33}$  is H; and  $R^{44}$  is an optionally substituted  $C_{3-6}$  monocyclic heteroaryl containing a Nitrogen



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atom, wherein the optional substituents are  $R^6$  groups;  $R^6$  is halogen,  $OR^{50}$ ,  $CF_3$ , or  $C_{6-12}$  monocyclic heterocycle containing at least one N, O or S atom; and  $R_{50}$  is  $C_{1-3}$  per fluoro.

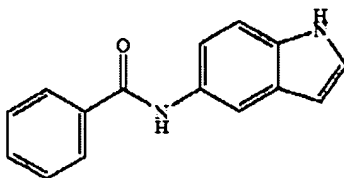


Frederickson et al. disclose the compound:

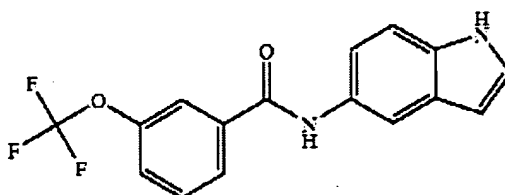
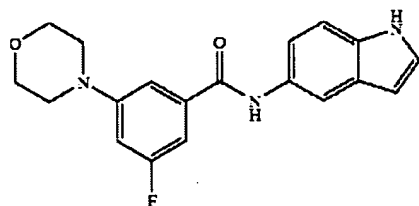
and

pharmaceutical compositions comprising the compounds (see p. 7, paragraph [0127]; p. 10, paragraph [0170]-[0181]; p. 17, Ex. 23.).

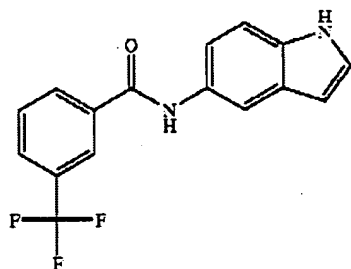
Frederickson et al. also disclose the following compounds which fall outside the



elected genus identified above:



and



(see p. 13, Ex. 13; p. 14, Ex. 14; and p. 15, Ex. 16 and 17).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-34 recites the limitation "pharmaceutical composition." There is insufficient antecedent basis for this limitation in the claim, because claim 25 is a "composition."

### ***Claim Objections***

(1) Claim 25 is objected to because of the following informalities: On page 8, in the second line of the page, the claims states, "N, O or 5 atom;" The "5" should be changed to "S." Appropriate correction is required.

(2) Claims 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the rejected base claim and any intervening claims.

(3) Claims 25 and 29-34 are objected to as containing non-elected subject matter.

(4) The amendment to the claims filed on 02/06/2007 does not comply with the requirements of 37 CFR 1.121(c) because a "marked up" version of the amended claims was not provided. For example, the formula (I) was deleted and a new formula was inserted. Also, in variable R<sup>44</sup>, "carboxyl" was amended to "carbonyl."

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending

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and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>re</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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KAMALA A. SAZED, Ph.D.  
PRIMARY EXAMINER

Joseph K. M<sup>re</sup>Kane  
Supervisory Patent Examiner, AU 1626  
Date: March 12, 2007